IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:
Lawrence E. Fosdick et al.
Application No. 10/685,125
Filed: October 13, 2003
Confirmation No. 4540
For: GLUCOSAMINE AND METHOD OF MAKING GLUCOSAMINE FROM MICROBIAL BIOMASS
Examiner: Elli Peselev
Art Unit: 1623
Attorney Reference No. 6682-65310-01

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DECLARATION UNDER 37 CFR § 1.132

LAWRENCE E. FOSDICK, PH.D., being duly sworn does hereby declare and affirm the following:

That he received a Bachelor of Science degree in Chemistry from Illinois Wesleyan University in 1976; that he received a Masters degree in Chemistry from the University of Nebraska in 1979; that he received a degree of Doctor of Philosophy in Physical Chemistry from the University of Georgia in 1987.

That he is a co-inventor of the invention claimed in Application No. 10/685,125 and that he is employed by Cargill Incorporated, the Assignee of Application No. 10/685,125.

That he was employed as a Quality Assurance Chemist in the pharmaceutical industry at Dorsey Laboratories, Lincoln, Nebraska, from 1978 to 1979; that he worked as an Analytical Chemist for Midwest Research Institute, Kansas City, Missouri, from 1979 to 1981; that he worked as a Senior Applications Chemist for EG&G Princeton Applied Research, Princeton, New Jersey, an instrument manufacturer, from 1981 to 1984; and that he worked as a Senior Research Chemist at Hercules Incorporated, Wilmington, Delaware from 1987 to 1996.

That he currently is a Research Fellow and has been employed by Cargill, Incorporated since 1996 where he leads the Research Chemistry Team in Eddyville Iowa, the Research Team comprising three to five chemists, most with advanced degrees. That his research specialties currently include analytical and process chemistry and that he actively participated in the initial development of the glucosamine production from conversion of chitin in fungal biomass process, from 2000 to 2001, and since 2001 continues to lead Cargill research further improving the developed glucosamine from fungal biomass chitin process.

That he has read the Examiner's obviousness rejections in regard to claims 20-23 in Application No. 10/685,125 in the Office action dated June 20, 2007. That he has read the Yang article (Yang *et al.*, Chinese *Agricultural Chemical Society*, (1998) 36(6), pp. 555-564). That he understands that the Yang reference does not disclose the processes recited in claims 20-23. That he understands that the Examiner is aware of the fact that the Yang reference does not disclose the same acid and temperature ranges as recited in the Cargill claimed process.

That because the Yang reference does not disclose the claimed process the Examiner's rejection of claims 20-23 under § 103(a) are based on a combination of Yang and an alleged knowledge of one of ordinary skill in the art to simply vary the acid concentration and temperature ranges. That he has read the proposed amendment of claims 20-23 as presented in the accompanying Amendment.

That the processes recited in claims 20-23 of Application No. 10/685,125 (of which he is an inventor) were extremely difficult, costly and time-consuming to develop as commercially viable processes. That he was in charge of leading the research team to develop the processes for producing the vegetarian glucosamine (*i.e.*, a glucosamine from fungal biomass so as to avoid the typical shellfish source of the available glucosamine products) such that the glucosamine product could be made on a commercial scale and could be sold at a price higher than the cost of its production. That the production of the recited glucosamine product has variable costs (*e.g.*,

H_2O, HCl, evaporation, and disposal of acid waste) and fixed costs (*e.g.*, costs of capital equipment) and that more complex processes than the recited and claimed processes, such as that disclosed by Yang, result in greater variable and fixed costs.

That fungal biomass chitin to glucosamine conversion processes are highly complex in part due to the multiple chemistries in the processes, which cannot be simply separated apart from one another and analyzed independently because the chemistries are inter-related and inter-twined to one another and compete to a certain extent due to the nature of the fungal biomass chitin source. Fungal biomass is comprised of chitin (a polymer of N-acetylglucosamine), glucans (polymers of glucose), plus proteins, lipids, salts. The glucans further comprise both linear glucans and highly branched glucans. Chemical reactions that may occur in processes for the production of glucosamine from fungal biomass include:

1. depolymerization of linear glucans to glucose
2. depolymerization of branched glucans to glucose
3. depolymerization of proteins to peptides and amino acids
4. depolymerization of chitin to N-acetylglucosamine
5. deacetylation of N-acetylglucosamine to glucosamine and acetic acid
6. degradation of glucosamine to hydroxymethylfurfural (HMF)
7. degradation of glucose to hydroxymethylfurfural (HMF)
8. degradation of HMF to levulinic acid plus formic acid
9. degradation of glucose + amino acids to insoluble Maillard products, commonly called melanoidins

These reactions may occur at different rates under the various combinations of acid concentration and temperature. For example, under certain process parameters reactions 1-5 and 7-9 may allow for production and recovery of glucosamine, while reaction 6 may result in loss of glucosamine. Other reactions may also become important depending on process parameters.

That it took his research team almost two years (18-24 months) of studying the fundamentals of the process of converting chitin in fungal biomass to glucosamine to understand the multiple chemistries in the reaction processes. That these studies were combined with months if not years of testing to develop the claimed processes.

That to develop the claimed processes he was involved in extensive laboratory testing and research in which multiple chemists conducted numerous test methods varying many different process parameters in order to make viable glucosamine compositions. That for more than 18 months, 2-4 research chemists and laboratory technicians performed at least 450 tests varying acids used, acid concentrations, temperatures, cook times, total solids, pressure parameters, etc., at both bench and pilot scale, to develop the currently claimed glucosamine composition processes. That many efforts were directed to reducing the amount of acid such as HCl used so as to reduce the amount of waste acid needed to be handled, treated and disposed of and to reduce worker safety risks, which were ultimately accomplished.

The undersigned declares that all statements made herein of his knowledge are true and that all statements made on information and belief are believed to be true and further, that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment under Section 1001 of Title 18 of the United States Code, and that any such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Executed at the place and date opposite the signature below.

Lawrence E. Fosdick
Lawrence E. Fosdick

At EDDYVILLE, IOWA
(City and State)
on this 22 day of OCTOBER, 2007.